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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 01/30/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,412

Applicant(s)

CONRAD, RICHARD C.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-61 are pending in the present application. This Office Action is responsive to Paper No. 9, filed 07 November 2002.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the grounds that both groups are drawn to a method for isolating poly(A) RNA and that a search for both groups would not present an undue burden to the Examiner. Applicant's argument is persuasive and the restriction requirement set forth in the Office Action mailed 01 October 2002 has been withdrawn. Accordingly claims 1-61 are currently under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 10-15, 18, 22-26, 28-30, 31, 33-42, 46, 47, 50, 53, 54 56-58 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Kearney et al. (US Patent No. 5,759,777).

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Kearney et al. teaches a method for isolating poly(A) RNA comprising using a mixture of tetramethylammonium chloride (TMAC) or tetraethylammonium chloride (TEAC) as an isostabilizing agent in a mixture with guanidinium. See entire document, especially column 6. Kearney et al. teach incubating the composition for at least four hours. See column 14, line 56. The poly(A) RNA is isolated by poly(T) affixed to a solid support such as beads. Kearney et al. also disclose that heating the mixture at temperatures ranging from 40°C to 95°C. The disclosure also teaches that various concentrations of isostabilizing agent, TMAC, was used is used in concentrations from 1M to 3M. See column 36, lines and column 12, lines 20-25 and columns 8-9. Kearney et al. on column 23, starting at line 18, teach derivitization with biotinylated labels.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4, 16, 17, 39-41, 45, 48, 49 are 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney et al.

Kearney et al. are relied upon as described above. Kearney et al. fail to disclose the specific ranges wherein the concentrations of the isostabilizing agents TMAC and TEAC fall.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the concentrations claimed by Applicant. Kearney et al. disclose

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concentrations in the range from 1.4M to 5M. Applicant claims ranges that fall within the claimed range such that it is well within the purview of one of ordinary skill in the art to optimize the amounts claimed.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05.

Therefore, the method would have been *prima facie* obvious to one of skill in the art at the time the invention was made.

Claims 1, 5, 10-15, 18, 20-26, 30, 31, 32, 36-38, 42, 46, 47, 50, 55-59 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney et al. as applied to claims 1, 5, 10-15, 18, 22-26, 30, 31, 36-38, 42, 46, 47, 50, 56-58 and 61 above, and further in view of Aviv et al. (PNAS Col. 69 no.6 1972 pp 1408-1412).

Kearney et al. are relied upon as described above. Kearney et al. fail to teach the isolation and purification of mRNA using cellulose.

Aviv et al. teach the isolation of poly(A) rich RNA by binding it to poly(dT)-cellulose, poly(U)-cellulose or nitrocellulose filters.

It would have been obvious to those of ordinary skill in the art at the time the invention was made to isolate poly(A) RNA using a structural composition such as cellulose to which

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poly(T) or poly(U) is attached and stabilizing compositions such as TMAC or TEAC. It has been known in the art for more than thirty years to use poly(U)-cellulose or poly(T)-cellulose to isolate poly(A) RNA. Given the routine nature of the technique in the art, the ordinary skilled artisan would be motivated to use a stabilizing agent such as TMAC or TEAC in order to facilitate hybridization between the poly(A) RNA and the immobilized poly(T) molecule and provide for a simplified sample preparation. The method also would provide for a more general temperature protocol for a wide range of tests because the hybrid melting temperature will not be as varied when TMAC is used because TMAC and TEAC strengthen A:T base pairs. Therefore, the invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 5, 10-15, 18, 22-27, 30, 31, 36-38, 42, 46, 47, 50, 51 56-58 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney as applied to claims 1, 5, 10-15, 18, 22-26, 30, 31, 36-38, 42, 46, 47, 50, 56-58 and 61 above, and further in view of Jacobs et al. (Nucleic Acids Research Vol.16 no.10 1998 pp4637-4650).

Kearney et al. are relied upon as described above. Kearney et al. fail to teach the use of sodium citrate.

Jacobs et al. teach sodium citrate to anneal oligonucleotides with TEAC and TMAC to increase the stability of the duplexes. See page 4640.

It would have been obvious to those of ordinary skill in the art at the time the invention was made to isolate poly(A) RNA using sodium citrate which facilitates the annealing of nucleic acids with, a structure to which poly(T) or poly(U) is attached and stabilizing compositions such

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as TMAC or TEAC. Jacobs et al. teach that TEAC and TMAC give added stability to nucleic acids annealed using sodium citrate solutions. One of ordinary skill in the art would have been motivated to use sodium citrate solutions to anneal the poly(A) RNA with the poly(T) molecule given the routine nature of the technique in the art. Moreover, the ordinary skilled artisan would be motivated to use a stabilizing agent such as TMAC or TEAC in order to stabilize the hybridization between the poly(A) RNA and the poly(T) molecule. Therefore, the invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 5, 10-15, 18, 22-26, 30, 31, 36-38, 42, 46, 47, 50, 56-58 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney et al. as applied to claims 1, 5, 10-15, 18, 22-26, 30, 31, 36-38, 42, 46, 47, 50, 56-58 and 61 above, and further in view of either Conlan et al. (Biotechniques Vol.27 no.5 1999 pp955-958).

Kearney et al. are relied upon as described above. Kearney et al. teach SDS as a detergent, however, fail to teach CHAPS or Triton X-100 detergents. See column 36, line 38.

Conlan et al. teach both Triton X-100 and CHAPS as non-ionic detergent. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize detergents such as Triton X-100 and CHAPS. One of skill in the art would have been motivated to use these detergents because they are known in the art to control protein aggregation. Moreover, one of skill in the art would have been motivated and reasonably expected success in substituting one detergent for another. In the instant case, it is within the purview of the ordinary skilled artisan to use Triton Z-100 and CHAPS instead of SDS.

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Therefore, the invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-9 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite a trademarked compound such that it is not clear what compound applicant intends to claim. Because a trademark or trade name is used to identify a source of goods, and not the goods themselves, overtime the compound or composition recited in the claims may change. Thus, trademark or trade name does not necessarily identify or describe the compound or composition associated with the mark.

If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). See MPEP 2173.05(t).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
January 27, 2003


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